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IN THE

Supreme Court of the United States

EBAY INC. AND HALF.COM, INC.,
Petitioners,

v.

MERCEXCHANGE, L.L.C.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF WISCONSIN ALUMNI RESEARCH FOUNDATION, AMERICAN COUNCIL ON EDUCATION, ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, CALIFORNIA INSTITUTE OF TECHNOLOGY, NDSU RESEARCH FOUNDATION, REGENTS OF THE UNIVERSITY OF CALIFORNIA, RESEARCH CORPORATION TECHNOLOGIES, TEXAS A&M UNIVERSITY SYSTEM'S OFFICE OF TECHNOLOGY COMMERCIALIZATION, UNIVERSITY OF VIRGINIA PATENT FOUNDATION AND WASHINGTON RESEARCH FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICI CURIAE* [1]

Amici are universities, entities affiliated with universities, the nation's higher education association, and entities involved in university technology management.[2] *Amici* engage in and support scientific research, obtain patents on inventions arising from the research, license the technologies to companies for commercialization and then use the licensing income to underwrite further academic research.[3]

The academic sector drives research and innovation in the United States. By 2002, the sector accounted for an estimated 54% of the basic research conducted in this country.[4] The nonprofit research community carries out much of this work under the Patent and Trademark Law Amendments of 1980, commonly known as the Bayh-Dole Act ("the Act" or "Bayh-Dole"),[5] and its implementing regulations (37 C.F.R. Part 401). Congress passed the Act in 1980 to (a) nurture

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[1] The parties have consented to the filing of this brief in global consents to the filing of amicus briefs in support of any party that have been lodged with the Clerk. Pursuant to Rule 37.6, *amici* state that no counsel for a party has written this brief in whole or in part and that no person or entity, other than these *amici* or their counsel, has made any monetary contributions to the preparation or submission of this brief.

[2] These entities are collectively referred to variously as "universities," the "academic sector" and/or "research institutions."

[3] In this brief, *amici* employ the shorthand term "technology transfer" to refer to this transfer of research results and new technologies from universities to the commercial marketplace.

[4] National Science Foundation, *Science and Engineering Indicators 2004*, *available at* http://www.nsf.gov/statistics/seind04/c5/c5s1.htm. In 2002, academic institutions spent $33 billion on research and development, of which $19 billion came from the federal government and $6.7 billion from the academic institutions themselves. National Science Foundation, *Science and Engineering Indicators 2004*, *available at* http://www.nsf.gov/statistics/seind04/c5/c5h.htm.

[5] Pub. L. No. 96-517, 94 Stat. 3019 (1980), codified at 35 U.S.C. §§ 200-212.

and spur research in the academic sector; and (b) promote university-industry collaborative relationships that would ensure that the fruits of university research reached and benefited the public.[6]

Amicus Wisconsin Alumni Research Foundation ("WARF") was founded in 1925 as a nonprofit entity to promote, encourage and aid scientific investigation at the University of Wisconsin-Madison ("UW-Madison"). One of WARF's first accomplishments was to patent a vitamin D discovery that eventually eliminated the childhood disease rickets worldwide. Since its founding, WARF has processed approximately 4,800 inventions created by UW-Madison faculty and staff, obtained 1,540 U.S. patents on these inventions, entered into over 1,390 license agreements with companies around the globe and returned $800 million in licensing fee income to UW-Madison to fund research programs and initiatives.

The Bayh-Dole Act has made it possible for WARF to make the contributions to the public good that it does today. In the middle to late 1960s, government agencies kept title to inventions that had been funded with federal money. As a consequence, invention disclosures to WARF had fallen to barely one per month, and what few disclosures there were had fallen in quality.[7] The situation improved somewhat when Institutional Patent Agreements ("IPAs") were negotiated with (what is now) the Department of Health and Human Services ("HHS") in 1968 and the National Science Foundation ("NSF") in 1973. These IPAs gave WARF (and

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[6] Entities such as *amici* that do not manufacture their inventions, but instead license them to the private sector for development and commercial marketing, sometimes are referred to in this brief as "non-manufacturing entities."

[7] An "invention disclosure" is a document prepared by an inventor to describe the invention made for use in a potential patent application.

other universities) the right to elect to take title to inventions made with funds from those two agencies.[8]

Since the enactment of Bayh-Dole, invention disclosures to WARF have mushroomed. Today, WARF (a) manages over 720 pending and 880 issued U.S. patents on UW-Madison technologies, as well as 1,920 foreign equivalents; (b) offers more than 3,800 technologies for licensing; (c) maintains more than 940 active commercial license agreements, as well as 460 academic licenses; (d) has over 160 license agreements with Wisconsin companies; and (e) holds equity in 40 UW-Madison spin-off companies. WARF's most important patents include the blood anticoagulant Warfarin; a coating process making pills easier to swallow; treatments for osteoporosis and cancer; magnetic resonance techniques; and a discovery known as the "Wisconsin Solution" that prolongs the use of transplant organs.

Amicus American Council on Education ("ACE"), founded in 1918, is the nation's coordinating higher education association. ACE is dedicated to the belief that equal educational opportunity and a higher education system are essential cornerstones of a democratic society. ACE's 1,800 members include accredited, degree-granting colleges and universities from all sectors of higher education and other education and education-related organizations. ACE is a forum for the discussion of major issues related to higher education and its potential to contribute to the quality of American life. ACE regularly represents its members before this Court, other federal courts, Congress and federal agencies.

Amicus Association of University Technology Managers ("AUTM") is a global network of members who represent more than 350 universities, research institutions, teaching

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[8] The IPAs were evolutionary steps that led to the Bayh-Dole Act. In essence, the terms and provisions of the Bayh-Dole Act codified IPA provisions.

hospitals and government agencies, as well as hundreds of companies involved with managing and licensing innovations derived from academic and nonprofit research. AUTM was founded in 1974 as the Society of University Patent Administrators to address a concern that inventions funded by the U.S. government were not being effectively commercialized. Through the years, AUTM has grown beyond this single objective and now provides professional development and networking opportunities for technology transfer professionals at all career levels and from established and newly forming organizations worldwide.

Amicus Board of Trustees of the University of Illinois ("University of Illinois") has a rich history of accomplishment and leadership in research and technology and its facilities include state-of-the-art laboratories to facilitate research and development. University of Illinois researchers conduct cutting-edge research in the fields of the life sciences, medicine, food and agriculture, animal sciences and veterinary medicine, engineering, the physical sciences, energy, the environment, computer science, software and information technology.

Inventions developed by University of Illinois researchers have led to numerous research awards, patents, and important commercial applications. The University of Illinois works with for-profit companies to transfer the benefits of its discoveries to the public. In 2004, the University of Illinois (a) filed 108 U.S. patent applications; (b) received notice of issuance of 59 U.S. patents; (c) executed 88 new licenses and license options; (d) maintained 164 active licenses and options; and (e) had a role in the formation and licensing of 16 start-up companies.

Amicus California Institute of Technology ("Caltech"), a small private university, has filed 1,137 nonprovisional patent applications and had 1,093 patents issue since October 1995. During that time period, it has granted over 300 licenses,

including 99 to Caltech start-up companies, and presently has 241 active licenses.

Amicus NDSU Research Foundation ("NDSU/RF") is an independent not-for-profit organization that supports research at North Dakota State University by facilitating the protection and licensing of intellectual property developed at North Dakota State University and assigned to NDSU/RF. Research is supported by distributing a portion of the licensing revenue to researchers as well as by other funding.

Amicus Regents of the University of California provides for technology transfer from ten campuses and five medical schools in the State, and from three national laboratories operated by the University of California system on behalf of the U.S. Department of Energy. Currently, there are more than 3,000 ongoing research projects supervised by 13,000 principal investigators.

In the last ten years alone, these efforts have led to three Nobel prizes and a long list of pioneering research discoveries in biochemistry, bioengineering, cell biology, disease procedures, developmental biology, endocrinology, genetics, immunology, neurobiology, oral biology, pharmacy and pharmacology. Those pathbreaking discoveries include: the hepatitis B vaccine; a human growth hormone; a method to treat aneurysms by use of a catheter instead of opening the skull; cochlear implants to help the hearing impaired; a method for detecting feline immune deficiency virus; a method for detecting chromosome abnormalities; a laser system to enhance treatment of skin conditions; and a new atomic force microscope.

Amicus Research Corporation Technologies is an independent technology management company that has been involved in providing commercialization services to academia and other institutions since its founding in 1912. It has been pivotal to the success of many important pharma-

ceuticals, diagnostics, biotechnology products, and new materials and processes. Recent products include three in the cancer area: the widely used therapeutic compounds Cisplatin and Carboplatin and the PSA (Prostate Specific Antigen) test for diagnosing and monitoring prostate cancer.

Amicus Texas A&M University System's Office of Technology Commercialization ("Office") manages the intellectual property for eighteen universities, state agencies and health science center on behalf of the State of Texas. The Office maintains a portfolio of more than 600 license agreements extending rights to industry partners for an effective transfer of technology for the benefit of the public. Additionally, it manages the prosecution and maintenance of more than 1,500 patents and patent applications.

Amicus University of Virginia Patent Foundation is a not-for-profit corporation that evaluates intellectual property generated in the course of research at the University of Virginia ("UVA"), seeks to protect those inventions that show commercial potential, and licenses those rights to industry. The Patent Foundation thus serves to promote the entry of UVA technologies into the commercial marketplace, which also generates royalty income to support additional research at UVA.

The Patent Foundation reviews and evaluates over 150 inventions per year. A third of those typically are successfully licensed to commercial partners for further development and commercial use. Of the inventions licensed to industry, almost half are licensed to UVA-affiliated start-up companies. Supporting the creation of local start-up companies and giving them licensing preference is a key component of the Patent Foundation's faculty service mission, and has the important benefit of promoting local economic growth.

Amicus Washington Research Foundation ("WRF") was founded in 1981 to assist universities and other nonprofit

research institutions in the State of Washington with commercialization of their technologies and to provide support, through gifts and grants, for scholarship and research. WRF is an independent private foundation whose operational revenue comes from retained funds from licensing and investing activities. WRF has given gifts and licensing disbursements to the University of Washington totaling more than $150 million.

WRF has benefited Washington State research institutions by licensing a variety of technologies to industry, including the basis for hepatitis B virus vaccine, blood clotting factors, recombinant insulin, and wireless technology supporting the "Bluetooth" protocol. The gifts from WRF have supported the creation of over 100 endowments for chairs, professorships, research fellowships and graduate stipends in science, medicine and engineering. Educational programs created and supported by WRF include the Center for Technology Entrepreneurship (University of Washington Business School) and the Program for Technology Commercialization (University of Washington Bioengineering). WRF was a founding supporter of technology "gap" funding programs at the University of Washington, the Fred Hutchinson Cancer Research Center, and Washington State University.

The academic technology transfer work required to accomplish these extraordinary results is always arduous, sometimes grueling, and for most institutions, only modestly remunerative. University of Michigan President Mary Sue Coleman recently explained why universities nonetheless engage in technology transfer:

> Many people are often confused about why we are interested in technology commercialization, in nurturing startup companies, and in facilitating more patents and license agreements.
>
> It is not about the promise of future revenues that might be generated from this activity.

> You heard me correctly. It is not about the money.... Technology transfer must serve our core mission: sharing ideas and innovations in the service of society's well-being.[9]

Amici submit this brief to provide the Court with an academic sector perspective on the technology transfer issues underlying this case. The brief focuses on the risks that limiting the availability of injunctive relief would pose to the technology transfer capabilities of the university sector and the continued vitality of the Bayh-Dole Act.

SUMMARY OF ARGUMENT

The Court should not modify the rule of law set forth in *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908), and its progeny on when it is appropriate to grant a permanent injunction against a patent infringer. Under those precedents, a patentee's non-use of an invention does not bar the issuance of a permanent injunction.

This rule is grounded in the constitutional and statutory right of patentees to exclude others from reaping the fruits of the patented inventions. It has made it possible for the university sector to grow and flourish through the licensing of its inventions and through investing in start-up companies that develop the inventions with the aid of private investors.

Neither the United States Constitution, the patent laws nor this Court's jurisprudence recognizes, let alone draws, any distinction between patentees that manufacture and those that license their patented inventions. Any distinction limiting the availability of permanent injunctive relief to the latter group of patentees would harm the university sector, and the start-up companies and other licensees on which universities

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[9] *AUTM U.S. Licensing Survey: FY 2004*, *available at* http://www.autm.net/surveys/dsp.surveyDetail.cfm?pid=28 (follow "Download PDF of abridged FY 2004 U.S. Survey Summary").

depend to develop and market their inventions for the benefit of the public.

Petitioners suggest that patents owned by entities that do not manufacture their inventions are less worthy of injunctive protection. Petitioners' rationale is that injunctions such entities currently can obtain against those that infringe their patents present a "growing problem for the economy." Br. 24.

In the academic research context, however, just the reverse is true. Congress enacted the Bayh-Dole Act in 1980 to encourage universities and other nonprofit institutions to develop patented technologies with federal funds and then partner with the private sector to commercialize the technologies for the public's benefit. This partnership has been extraordinarily successful, with hundreds of blockbuster drugs and other products put in the stream of commerce, all to the benefit of society in the form of new products and processes. Narrowing the availability of permanent injunctive relief would harm the economy and undermine the purpose of the Act.

Making it more difficult for non-manufacturing entities like universities to obtain permanent injunctions also would reduce the leverage the academic sector needs to negotiate reasonable licensing agreements with potential licensees. Limiting injunctive relief similarly would mean that the academic sector could no longer count on the right to exclusive use of an invention that the availability of an injunction protects. Universities need such certainty to form and invest in start-up companies built on university inventions.

So do investors: if injunctions were not available, investors would shy away from such ventures. This in turn would discourage the formation of start-up companies to advance early stage technology, make it more difficult to obtain the necessary equity, and limit the development of such innovative companies. Such a consequence would undercut the

universities' constitutional and statutory right to exclude and would undermine the Bayh-Dole Act.

ARGUMENT

INTRODUCTION

A recurring theme in petitioners' brief, and those of its supporting *amici*, is that non-manufacturing entities threaten to become a plague on modern society and that this Court's long-standing approach to permanent injunctions only makes matters worse. According to petitioners (Br. 47), the "relevant economic contexts" have changed dramatically since this Court's 1908 *Continental Paper Bag* decision. As goods and services have become increasingly complex and technology has advanced, "a patent holder's ability to leverage and abuse an automatic entitlement to an injunction" supposedly has increased. *Id.* Unless this Court intervenes, petitioners warn, untold harm will befall not only "innocent employees and consumers," but also vital parts of the economy, "such as the capital markets and the banking system." *Id.*[10]

In what follows, *amici* show that petitioners' doomsday scenario has no basis in fact or law. There is no constitutional, statutory or precedential support for the limits on injunctive relief petitioners suggest should be placed on patentees that license, but do not manufacture their inventions. To the contrary, Congress has expressly encouraged the academic sector to license its inventions. Moreover, university research *drives*, not harms, today's technology-based economy and, without the availability of injunctive

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[10] Petitioners first lump non-manufacturing entities with "professional patent litigators," but then appear to try to draw a line between non-manufacturing entities that develop and license patents, and those that do not. *Id.* Petitioners do not explain how a principled line can be drawn between "good" and "bad" non-manufacturing entities.

relief, research institutions like *amici* and their licensees will be harmed, contrary to the intent of Congress and the public interest.

I. ALL PATENTEES SHOULD CONTINUE TO HAVE THE SAME RIGHT TO PERMANENT INJUNCTIVE RELIEF

Article I, § 8, cl. 8 of the United States Constitution empowers Congress to promote the progress of the "useful Arts" by giving inventors "the exclusive Right to their . . . Discoveries" for a limited period of time. Congress exercised that power by conferring on *every* patentee "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited term. 35 U.S.C. § 154(a)(1)-(2). A patent accordingly carries with it "the right to exclude others from making, using, or vending the thing patented without the permission of the patentee." *United Shoe Mach. Corp. v. United States*, 258 U.S. 451, 463 (1922); *see Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.").

As explained at length in the brief of *amici curiae* American Intellectual Property Law Association and Federal Circuit Bar Association (at 21-23), when it comes to the exercise of this right to exclude, neither the Constitution nor the patent law picks and chooses among patentees so as to disfavor those that do not use their patents. Moreover, Congress repeatedly has rejected efforts to alter this statutory policy and limit this right by imposing a forfeiture or compulsory licensing penalty on such patentees. *Id.* at 22-23.

As demonstrated below, any deviation from this well-settled law would harm the university sector in particular. Nonprofit research institutions and their licensees depend on

outside investors. Such investors would be reluctant to underwrite the costly development of inventions without the certainty that competitors would not rob them of the fruits of their inventions through infringement.

II. TREATING NON-MANUFACTURING ENTITIES AS SECOND-CLASS PATENTEES WOULD BE CONTRARY TO THE BAYH-DOLE ACT AND THREATEN THE ACT'S CONTINUED SUCCESS

A. The Impetus Behind The Act

The Bayh-Dole Act grew out of the crisis in productivity faced by the United States beginning in the 1970s. H.R. Report No. 96-1307(I) (1980) ("H.R.") at 1-2, *as reprinted in* 1980 U.S.C.C.A.N. 6460, 6460-61. As explained in the House Report accompanying the bill:

> Many analysts of the U.S. economy have warned that the roots of the current recession lie in a longer term economic malaise which arises out of a failure of American industry to keep pace with the increased productivity of foreign competitors.
>
> . . . There has been an especially significant decline in total U.S. expenditures for research and development, as measured in constant dollars since 1970. Since the primary means of improving productivity lies in the creation of new technologies, the decline in expenditures for research and development is especially significant to the health of the overall economy.

Id. (footnotes omitted).

For that reason, "the effective commercialization of government financed research" was becoming an "ever more important issue for those who [were] concerned with Industrial innovation," and "[s]pecial emphasis was placed on the role of the patent system and the patent policy regarding

government funded research in promoting industrial innovation." *Id.* at 2, *as reprinted in* 1980 U.S.C.C.A.N. at 6461.

B. The Purpose And Goals Of The Act

The policy and objective of the Bayh-Dole Act are set out in the first section of the Act: "[T]o use the patent system to promote the utilization of inventions arising from federally supported research or development." 35 U.S.C. § 200. The Act is designed to "encourage private industry to utilize government funded inventions arising through the commitment of the risk capital necessary to develop such inventions to the point of commercial application." H.R. at 3, *as reprinted in* 1980 U.S.C.C.A.N. at 6462. The Act specifically

> addresses the special needs of Universities and small businesses when they attempt to deal with patent issues arising out of government contracts. Both of these groups lack the resources to cope with the bewildering regulatory and bureaucratic problems associated with transfer of patent rights pursuant to government contracts; and the university sector in particular is an important link to the private sector.

Id.

A primary goal of the Act is to ensure that the patent system promotes "collaboration between commercial concerns and nonprofit organizations, including universities," and that "inventions made by non-profit organizations and small business firms are used in a manner to promote free competition and enterprise." 35 U.S.C. § 200. To that end, the Act gives "preferential treatment" to "[n]on-profit research institutions and small businesses" by means of a statutory presumption that such entities, and not the federal government, hold title to any inventions funded in whole or in part by the federal government. H.R. at 5, *as reprinted in* 1980 U.S.C.C.A.N. at 6464.

C. The Act's University-Private Sector Partnership Has Been An Unqualified Success

It is not farfetched to view the Act as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century," and one that "helped to reverse America's precipitous slide into industrial irrelevance."[11] The university sector's experience over the past twenty-five years is a testament to the Act's success. During that time, the number of U.S. patents issued to universities and the number of universities engaging in technology transfer activities have increased exponentially. The economic impact of the commercialization of the universities' new technologies has been just as dramatic. By 2000, they had added over $30 billion to the U.S. economy, created 250,000 jobs and led to the spin-off of over 2,200 new companies.[12]

The Act (and its predecessor IPAs with HHS and NSF) also have led to many cutting-edge science and technology breakthroughs by the university sector which have been of immeasurable value to the health and welfare of the public. In addition to those *amici* have made, such breakthroughs include MRI body scanning (State University of New York at Stony Brook), the vaccine for hepatitis B (Institute for Cancer Research) and the technique behind Google's search engine (Stanford University).

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[11] *Innovation's Golden Goose*, The Economist, Dec. 14, 2002.

[12] *See, e.g.*, Q. Todd Dickinson, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Remarks at the National Academies: Board on Science, Technology and Economic Policy, at 3 (Feb. 2, 2000), *available at* http://72.14.207.104/search?q=cache:QbatTS5jyYwJ:www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/academies.pdf+Todd+Dickinson+Board+on+Science+technology+and+Economic+%2430+billion&hl=en&gl=us&ct=clnk&cd=2.

Data from the recently released *AUTM U.S. Licensing Survey: FY 2004*[13] further confirm the effectiveness of the Act and the importance of the university-private sector partnership it created:

> *Patents and Technology Licensing*: In 2004, universities received more than 3,600 U.S. patents. Less than 250 were issued to universities in 1980, the year Congress passed the Bayh-Dole Act. Universities entered into 4,783 new licenses and had 27,322 active licenses in 2004.[14]
>
> *License and Royalty Income Earned to Support Further Research*: License income in 2004 was $1.385 billion, with royalties on product sales $1.122 billion. The bulk of this income supports the university sector and academic research.
>
> *Products Brought to Market*: Over 500 products based on university or nonprofit research results came on the market in 2004. Since 1998, over 3,100 new products have entered the marketplace. More than 300 biotechnology drug products, and vaccines targeting more than 200 diseases—including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis—are in clinical trials.[15] This continued

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[13] http://www.autm.net/surveys/dsp.surveyDetail.cfm?pid=28 (follow "Download PDF of abridged FY 2004 U.S. Survey Summary").

[14] These figures include options to take a license, as well as executed license agreements.

[15] This product development activity contrasts sharply with the level before the Bayh-Dole Act, when the government held title to patents discovered with federal funding. A 1968 study found that *no* drug on which the government held the patent had *ever* been commercially developed and become available to the public. *AUTM U.S. Licensing Survey: FY 2004*, *available at* http://www.autm.net/surveys/dsp.surveyDetail.cfm?pid=28 (follow "Download PDF of abridged FY 2004 U.S. Survey Summary"). By 1980, 28,000 government-funded patents lay on the shelf gathering dust, as the federal government had licensed less than 5% of the patents to which it held title for commercial development. *Id.*; GAO

momentum in the rate of new product introductions is one of the most concrete measures of public benefit from technology transfer.

Start-up Companies: Nearly 68% of the new licenses were taken by newly formed or existing small companies (fewer than 500 employees), and over 90% of these licenses were exclusive. Since 1980, U.S. universities, hospitals and research institutes have spun off 4,543 companies based on licenses from those institutions. Two-thirds of these companies are still operating. This very high survival rate demonstrates the successful application of these technologies in the market.

In view of the success of the Bayh-Dole Act and the technological and innovative contributions to the economy made by the academic sector, petitioners' notion that such non-manufacturing entities wreak havoc with the economy such that their right to injunctive relief should be curtailed has no basis in fact. Nor does it have any legal foundation: Congress singled out research institutions for "preferential treatment" in the Bayh-Dole Act, and made it *easier*, not more difficult for research institutions to license instead of manufacturing their inventions.

D. Without Injunctive Relief, Universities Would Find It More Difficult To License Their Inventions

Compared to their industry counterparts, universities come to the bargaining table at a distinct economic and tactical disadvantage. Unlike industry patent holders, university licensors rarely are capable of directly commercializing the patented technologies. Patent licensing is often the main, if not the only way universities can fulfill their obligations

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Report, *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities*, at 3 (May 7, 1998).

under Bayh-Dole and transfer their patented innovations for the benefit of the public.

Major potential private sector licensees believe (with some justification) that universities have neither the resources nor the stomach for expensive and protracted patent litigation. Without the leverage of injunctive relief, a potential licensee might well conclude that willful infringement makes more economic sense than taking a license. *See, e.g., Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1158 (6th Cir. 1978). Such a gamble would be even more worthwhile if the current licensee were a relatively small company and the infringer wanted to dominate the market. The negative impact on university technology transfer could be substantial, and the effect upon innovation and the benefits it conveys to the public equally adverse.

The availability of injunctive relief shields the academic sector from such an outcome. Injunctive relief gives an academic sector patent owner leverage in persuading a private sector entity to risk the money needed to develop a product or technology and bring it to market. The risk of a permanent injunction enforcing the right to exclude is a powerful deterrent for potential infringers and motivates those that acquire a license to risk money on development and commercialization. Such an incentive for potential investors, and such a deterrent for potential infringers, is particularly important to university licensors.

E. Restricting Injunctive Relief Also Would Have A Negative Impact On The Small Companies On Which Universities Depend To Bring Their Inventions To The Public

A corollary goal of the Bayh-Dole Act is to stimulate small business development through the commercialization of federally funded university inventions: "It is the policy and objective of the Congress to . . . encourage maximum par-

ticipation of small business firms in federally supported research and development efforts; . . . ." 35 U.S.C. § 200. This policy objective is now being reached, as every State looks to its universities as engines of innovation and economic development that will spin off start-up technology companies. Hotbeds of innovation already exist in the San Francisco Bay, San Diego, Boston, Washington, DC and Atlanta areas. *Amici* alone have taken equity in hundreds of start-up companies, all founded to develop federally funded inventions.

Each of these companies required at least some degree of exclusivity in its license agreements. Congress implicitly recognized that exclusivity was required to assure investors that investing was a reasonable risk. Indeed, Congress amended the Bayh-Dole Act in 1984 to expand the ability to grant exclusive licenses.[16] With these exclusive rights, investors could be assured of an opportunity to make a reasonable return on their investment. Without them, investors would not risk the investment.[17] If universities could not enjoin infringement, it is unlikely that the start-ups and other licensees would have flourished and had such an impact on the economy.

Exclusive rights are particularly important in the development of therapeutics (such as pharmaceuticals or medical devices). Therapeutic products are highly regulated and take

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[16] *See* Pub. L. No. 98-620, Title V, 98 Stat. 3335, 3364 (1984).

[17] In Senator Bayh's words, the Act was intended to make it possible for university patents to "be licensed to businesses who then had the incentive to invest the resources necessary to develop the idea and make it available to the consumers. Often the investment required tens, if not hundreds, of millions of dollars before the product reached the market. Without ownership rights, there would be no incentive to invest." AUTM, *Technology Transfer Stories: 25 Innovations That Changed the World*, at 11 (2006), *available at* http://www.betterworldproject.net (follow "Download PDF Files of Printed Reports").

years and tens to hundreds of millions of dollars to develop. Without assurance of exclusivity, pharmaceutical companies would not develop them. With every passing year, more large pharmaceutical companies exit the therapeutic discovery business and instead license the technology from universities or small companies, or acquire small companies themselves.

Approximately 39% of new drugs approved by the FDA from 1998 to 2003 originated from outside pharmaceutical companies—24% came from public research.[18] If exclusivity and the right to enjoin infringers had not been available to universities because they did not directly commercialize the inventions, a significant number of new drugs would never have gotten to market, all to the detriment of the public health and the goals of the Bayh-Dole Act.

CONCLUSION

The judgment should be affirmed.

Respectfully submitted,

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[18] *See* Robert Kneller, *The Origins of New Drugs*, 23 Nature Biotechnology 529, 529 (May 2005).